

REMARKS

This Amendment is made in response to the Office Action dated June 22, 2007. Claims 94-107 are pending in the application. By this Amendment, claims 94, 101 and 105 have been amended to clarify that the filter element is adapted to move from an expanded position to a collapsed position by initially drawing the filter edge into a restraining sheath/catheter and thereafter the central region to move at least a portion of the filter element into the restraining sheath/catheter. The specification has been amended to include the term "filter membrane." It is believed that no new matter has been added to the specification. Favorable reconsideration is respectfully requested.

The Examiner has rejected claims 94-113 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner bases the rejection on the basis that the term "membrane" never appears in the specification to be enabling to one of ordinary skill in the art. Applicants strongly disagrees with the Examiner's position. The term "membrane" would be readily understood to one skilled in the art as a thin, pliable sheet, layer or film. The specification clearly describes the term "filter element" as constituting a thin, pliable sheet, layer or film or "membrane" as the term is understood in the art. However, in order to expedite allowance of these claims, Applicants have amended the specification to reference the term "membrane." It is believed that no new matter has been introduced into the specification. Accordingly, Applicants respectfully request the Examine to withdraw the Section 112, first paragraph rejection of the pending claims.

Claims 94-107 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,800,457 to Gelbfish (the "Gelbfish patent"). Applicants note that the presently claimed invention is directed to a filter element, an embodiment of which is shown in Figures 41 and 42 of the application. The term "filter element," as used in the present claims and the specification, is directed to the membrane portion of the embolic protection device which captures the embolic debris released in the body vessel. All of

the pending claims recite a central portion having a plurality of perfusion openings. Applicants note that the only portion of the filter device disclosed in the Gelbfish patent which constitutes a filter membrane is the element referred to as a "web or film 166" or "membrane 172." The film 166 and membrane 172 do not include a plurality of openings adapted to allow blood to flow therethrough while capturing embolic debris. Rather, a large single opening, adjacent to this continuous web or film 166 and membrane 172, is connected to a debris removal instrument and used to draw fluid and collected material out of the patient utilizing suction. The web or film 166 and membrane 172 of the Gelbfish device lack any type of perfusion openings. In fact, the Gelbfish patent actually teaches away from the use of perfusions openings in the web or film 166 and membrane 172. The Gelbfish patent states the following at column 11, line 61- Column 12, line 1:

Filter body 148 is provided with a web or film 166 which renders the filter body **liquid impermeable** at least at its downstream side. Web or film 166 **enhances the transmission of suction forces** during a debris removal operation, as discussed above. [emphasis added]

Therefore, there are no openings in this "web or film 166" and "membrane 172" since this particular component is designed to remain liquid impermeable to enhance the transmission of suction forces. The openings which the Examiner states are present in the Gelbfish device are not openings in the membrane portion, i.e. the web or film 166 and membrane 172, and are not used to capture embolic material. These openings (space between struts 150) in the Gelbfish device must allow the free flow of fluid and embolic material into the sleeve 154 which is connected to the debris removing equipment. These openings simply do constitute a portion of the web or film 166 or membrane 172 and certainly do not filter any embolic debris. Accordingly, the Gelbfish patent fails to disclose the structure recited in the pending claims. Applicants also note that, in order to expedite allowance of this case, independent claims 94, 101 and 105 have been amended to specify that the presently claimed filter element is adapted to move from an expanded position to a collapsed position by initially drawing the filter edge into a restraining sheath/catheter and thereafter the central region to move at least a portion of the filter

element into the restraining sheath/catheter. This particular structure is lacking in the Gelbfish device since the distal most edge of the Gelbfish device does not initially enter the sleeve 154.

Accordingly, the Gelbfish patent fails to disclose the structure of the pending claims. Applicants respectfully request the Examiner to withdraw the Gelbfish patent as an anticipatory reference.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Please charge any fees payable in connection with this response to Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

By: /Thomas H. Majcher/
Thomas H. Majcher, Reg. No. 31,119

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